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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,180	02/13/2002	Robert J. Hariri	009516-0050-999	9742

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,180	HARIRI, ROBERT J.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54 and 60-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54 and 60-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response and amendment filed April 19, 2005 have been entered. Claims 54, 62-64 have been amended. Claim 69 is newly submitted. Claims 54, and 60-69 are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims and response will not be reiterated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, and 60-68 stand rejected, and claim 69 is newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and following.

In the response, Applicants first argue that the specification teaches how to deplete endogenous cells at page 27, lines 2-12, and such technique is known by virtue of at least one publication, i.e. US 2002/0160510. Applicants went on pointing to various pages of the specification for cell and nutrients delivery, and harvest.

In response, the specification only *prophetically* outlines and briefly refers to what is known in the art for depleting endogenous cells in a biological tissue in general at page 27, lines 2-12. As indicated in the previous Office action, the referred art did not teach how to deplete endogenous cells from an intact placenta having a significant size/volume and complicated multi-layer sac structure. The Office cited *Badylak et al* indicating the importance of preserving the structure and tissue strength when using the UV, and X-ray irradiation methods for treating biological tissue, and gave detailed reasoning as to why more specific guidance are needed (e.g. see pages 6-7). The referred publication of the U.S. patent application is applicant's own disclosure and was not incorporated into the instant application as filed. Moreover a basic enabling disclosure should not simply refer to another application. The Federal Circuit has stated that:

> A specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, **when there is no disclosure** of any specific starting material **or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.** It is the specification, **not** the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

In the instant case, the method of making the claimed placenta is essential for practice the claimed invention, and thus should not be omitted by referring to prior art, which did not teach culturing exogenous cells in a whole or partial placenta. As to the technical details, even though the delivery of exogenous cells intending to culture and nutrients supporting the cell growth is not an issue, the Office had indicated the severe limitations in maintaining the past-partum mammalian plasenta, and limitations of growing cells on the placenta tissue (pages 5-9). Such limitations are explicitly or implicitly taught by *Stromberg et al, Ma et al, Contractor et al, Tseng, Madri et al,* and *Kleinman et al.* The specification and the remarks failed to address the issues, and thus fail to provide an enabling disclosure for the claimed invention.

Concerning *Kleinman* and *Tsang* references, it is apparently well known in the art that the placenta tissue extract or membrane could support the growth of various exogenous cells. Although *Kleinman et al* or Tsang do not explain why they use human placenta extract (matrigel) or membrane rather than the whole placenta, it would have been obvious to the skilled artisan that due to the structural characteristics, a whole placenta would be too difficult to manage and impractical to use as a cell culture support in view of the levels of the skilled in the art and the numerous teachings cited.

On another front, the reason *Kleinman et al* brought up the immune rejection issue is because the cultured cells may be used for transplantation, thus the remnants of the placenta extract may cause immune rejection even though the *in vitro* cultivation process won't.

Applicants then argue that nothing in Stromberg suggests that tissue necrosis or similar problems would be experienced in the perfusion of a complete placenta, thus the reference is irrelevant in assessing the enablement of the current claims.

In response, since the intended use of the claimed invention does not stop at the perfusion step, the reference is relevant. A perfused placenta comprising an exogenous mammalian cell requires a process of cultivating exogenous cells in and on the placenta, requires prolonged maintenance of the placenta. *Stromberg et al* (Methods in Cell Biol 1980,21:227-52) teach when a fragment of a placenta (dissected chorionic villi) is submerged in the medium, the necrosis could occur in the central areas of the tissue fragment about 1-2 mm in size. Even with the improved method introduced by the author, the size could only maximized to 1-1.5 cm (1st paragraph, page 235). Hence, it would have been suggested to the skilled in the art that it is impractical to maintain an intact placenta *in vitro* for an extended period of time required for propagation of exogenous cells without significant necrosis and deterioration of the placenta itself. The specification fails to address these issues, and thus fails to provide a sufficient guidance to a person of skill intending to practice the claimed invention.

Applicants went on to argue since nowhere in the specification does it require more than seven days of perfusion, the *Ma* reference is irrelevant. In response, again, since the intended use of the claimed invention does not stop at the perfusion step, the reference is relevant because cultivation of exogenous cells requires extended period of time.

Applicants then argued Contractor teaches only the culture of placental lobules, not whole placentas. In response, *Contractor et al* (Cell Tis Res 1984;237:609-17, e.g. abstract) teach even under nutritional perfusion, oedema and microvillous damage appeared after *three hours* of placenta perfusion. Such teaching would have reasonably suggested to the skilled artisan that it would be at the least equally difficult if not more to maintain the whole placenta since much more tissue are involved for nourish, and for nutrient to penetrate. In view of such teaching, it is unlikely that the exogenous cells could be efficiently propagated, and thus the specification fails to provide an enabling disclosure for the claimed invention.

Applicants argued that Sanders et al appears to relate that placental culture for several days is feasible. In response, *Sanders et al* perfused the placenta for biological substances secreted by the post-partum placenta, and do not teach culturing exogenous cells using the whole placenta.

Applicants then alleged that the Office asserted legally insufficient standard to reject claims for non-enablement.

In response, the legal standard for evaluating the enablement of instant claims are how to make and use the claimed placenta comprising an exogenous mammalian cells, the specific questions applicant's referred to reflect the explanation and reasoning as to why the specification failed to provide an enabling disclosure for the intended use, and why it is impractical to use the whole placenta as culture support. Such conclusion was drawn from and supported by numerous pre- and post-filing art of record, and thus the analysis is legally sufficient. The following is an example in MPEP as to what has

been set forth as a legal standard for evaluating the enablement of a claimed invention. According to MPEP as pursuant to an enabling disclosure required by 35 U.S.C 112, first paragraph,

"AN APPLICANT'S SPECIFICATION MUST ENABLE A PERSON SKILLED IN THE ART TO MAKE AND USE THE CLAIMED INVENTION WITHOUT UNDUE EXPERIMENTATION.(...) AS SUCH, THE DISCLOSURE MUST TEACH A PERSON SKILLED IN EACH ART HOW TO MAKE AND USE THE RELEVANT ASPECT OF THE INVENTION WITHOUT *UNDUE* EXPERIMENTATION. FOR EXAMPLE, TO ENABLE A CLAIM TO A PROGRAMMED COMPUTER THAT DETERMINES AND DISPLAYS THE THREE-DIMENSIONAL STRUCTURE OF A CHEMICAL COMPOUND, THE DISCLOSURE MUST

- ENABLE A PERSON SKILLED IN THE ART OF MOLECULAR MODELING TO UNDERSTAND AND PRACTICE THE UNDERLYING MOLECULAR MODELING PROCESSES; AND
- ENABLE A PERSON SKILLED IN THE ART OF COMPUTER PROGRAMMING TO CREATE A PROGRAM THAT DIRECTS A COMPUTER TO CREATE AND DISPLAY THE IMAGE REPRESENTING THE THREE-DIMENSIONAL STRUCTURE OF THE COMPOUND.

IN OTHER WORDS, THE DISCLOSURE CORRESPONDING TO EACH ASPECT OF THE INVENTION MUST BE ENABLING TO A PERSON SKILLED IN EACH RESPECTIVE ART. (MPEP 2106.B.2)

According to this standard, the specification must show the claimed placenta is indeed able to be maintained for an extended period of time and support the growth, cultivation of a desired type of exogenous cells uniformly, and the cultivated cells must be readily harvested and isolated from the placenta support.

MPEP also teaches, "DETERMINING ENABLEMENT IS A QUESTION OF LAW BASED ON UNDERLYING FACTUAL FINDINGS". IN RE VAECK, 947 F.2D 488, 495, 20 USPQ2D 1438, 1444 (FED. CIR.1991); ATLAS POWDER CO. V. E.I. DU PONT DE NEMOURS & CO., 750 F.2D 1569, 1576, 224 USPQ 409, 413 (FED. CIR. 1984). One such factual evidence to be considered is "IF LITTLE IS KNOWN IN THE PRIOR ART ABOUT THE NATURE OF THE INVENTION AND THE ART IS UNPREDICTABLE, THE SPECIFICATION WOULD NEED MORE DETAIL AS TO HOW TO MAKE AND USE THE INVENTION IN ORDER TO BE ENABLING. THE "PREDICTABILITY OR LACK THEREOF" IN THE ART REFERS TO THE ABILITY OF ONE SKILLED IN THE ART TO EXTRAPOLATE THE DISCLOSED OR KNOWN RESULTS TO THE CLAIMED INVENTION. IF ONE SKILLED IN THE ART CAN READILY ANTICIPATE THE EFFECT OF A

CHANGE WITHIN THE SUBJECT MATTER TO WHICH THE CLAIMED INVENTION PERTAINS, THEN THERE IS PREDICTABILITY IN THE ART. ON THE OTHER HAND, IF ONE SKILLED IN THE ART CANNOT READILY ANTICIPATE THE EFFECT OF A CHANGE WITHIN THE SUBJECT MATTER TO WHICH THAT CLAIMED INVENTION PERTAINS, THEN THERE IS LACK OF PREDICTABILITY IN THE ART. ACCORDINGLY, WHAT IS KNOWN IN THE ART PROVIDES EVIDENCE AS TO THE QUESTION OF PREDICTABILITY. As seen from applicant's arguments, none of the references on record teaches how to culture cells in a whole placenta; accordingly, any reasonable extrapolation of the prior art would lead to the conclusion that it is not feasible to conduct cell culture on a whole placenta at the time of filing and to the present day. Therefore, it is incumbent upon applicants to provide sufficient and enabling teachings within the specification for the claimed invention. Although the instant specification contemplates using a mammalian placenta for cell culture, it is not enabled for doing so because it fails to address the art known hurdles on how to use an intact placenta for cell culture in light of the cited art of record. Apparently, the general knowledge and levels of skill in the art do not supplement the omitted description, because specific, not general guidance is what is needed.

To this end, it is further noted the specification lacks working example or fails to disclose, reduced to practice, a placenta comprising an exogenous mammalian cell. MPEP teaches, ""WHEN CONSIDERING THE FACTORS RELATING TO A DETERMINATION OF NON-ENABLEMENT, IF ALL THE OTHER FACTORS POINT TOWARD ENABLEMENT, THEN THE ABSENCE OF WORKING EXAMPLES WILL NOT BY ITSELF RENDER THE INVENTION NON-ENABLED." "LACK OF A WORKING EXAMPLE, HOWEVER, IS A FACTOR TO BE CONSIDERED, ESPECIALLY IN A CASE INVOLVING AN UNPREDICTABLE AND UNDEVELOPED ART." (MPEP 2164.02, 03) In the instant case, since none of the disclosed art teaches culturing a cell in a whole placenta, and all of the cited

art of record pointing to non-enablement of making the claimed invention, lacking a working example in the instant disclosure is a factor to be considered as non-enabling.

Applicants then reasoned since *Tseng et al* teaches placenta material has supporting power for growing living cells, the examiner's contention is therefore without basis, and requested an examiner's declaration. In reply, the Office has repeatedly indicated the well-known knowledge concerning the supporting power of placenta membrane (*Tsang et al*) or extract (*Kleinman et al*). The question raised is whether culturing desired cells in an intact whole placenta as claimed is feasible. The doubts and the conclusion of non-enablement were drawn from and supported by numerous art of record, thus it is not necessary to provide an examiner's declaration.

Accordingly, for reasons of record and set forth *supra*, the specification fails to meet the statutory enablement requirement, and the rejection stands.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 and 60-68 stand rejected and claim 69 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim recitation "a cell which is neither fetal nor maternal in origin". Since all cells in a mammalian subject is originated from a fetus in the uterus of a mother, it is unclear what type of cells the

instant claims refer to, encompass or exclude, thus, the metes and bounds of the claim is uncertain.

In the response, applicants cited a dictionary for the general definition of "origin", and argued that the phrase means "a cell that is not obtained from a fetus or the mother of that fetus". Such circular teaching has not clarified the claims. Here again, all cells in a mammalian subject are originated from a fetus in the uterus of a mother, thus they would be either fetal or maternal in origin. Since applicants appear to refer such cells as cells derived from a different individual compared to the claimed placenta, the claim should be amended to that effect.

The new claim 60 recites "an exogenous mammalian cell which is neither fetal nor maternal in origin", deleting the phase "which is neither fetal nor maternal in origin" would obviate this rejection.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54 and 68 stand rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *MacLaren et al* (J Comp Pathol 1992).

Applicants first argue that *MacLaren* does not teach a post-partum placenta comprising a cell that is not fetal or maternal in origin because a post-partum placenta contains no fetus, and thus contains no exogenous cells.

In response, *MacLaren et al* indeed teach a post-partum placenta which is collected at the full term pregnancy, wherein the placental membranes were passed naturally (post-partum, page 281, 3rd paragraph). Here, claims do not contain a limitation that requires an exogenous cell, and the inter-species/intra-species cells are neither fetal nor maternal in origin. Further, the post-partum placenta is extra-embryonic, which is not fetal, because fetal as it relates to fetus defined as the unborn young from the end of the eighth week after conception to the moment of birth, as distinguished from the earlier embryo in humans. Thus the post-partum placenta is not really maternal or no longer belongs to the mother (post-partum). Thus, the placenta disclosed by *MacLaren et al* meets claim limitation.

Applicants then argue the Examiner provides no support for rinsed placenta would be blood less. In response, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the

contrary, the burden is upon the applicant to prove that the prior art products do not necessarily or inherently possess characteristics of claimed product, which requires factual evidence demonstrating that actual, unobvious differences exist (or that the claimed products are functionally different than those taught by the prior art) and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPBI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922, 1923 (BPAI 1989).

Applicants went on to argue that the examiner has not explained how the claimed placenta is obvious over the placentas shown in MacLaren. In response, it was indicated the placenta disclosed even if not bloodless after rinsing and has not undergone the perfusion process, the perfusion does not change the structure of the placenta, only rinses away cord blood remained in the placenta after birth. Since the cord blood is not part of the placenta structure, even if there were cord blood cells remaining in the rinsed placenta, the structure and function of the placenta is not patentably distinct from the bloodless placenta. Accordingly, the bloodless mammalian placenta as claimed appear to encompass the placenta disclosed by *MacLaren et al.* Accordingly, instant claims are anticipated or in the alternative obvious over *MacLaren et al.*

Claims 54, 60-65, 68 stand rejected under 35 U.S.C. 103(a) as obvious over *MacLaren et al* (J Comp Pathol 1992), in view of *Sanders et al* (US 3,862,002), and

Stromberg et al (Methods in Cell Biol 1980;21B:227-52), and as evidenced by *Larsson et al* (Angiogenesis 2002;5:107-10).

Applicants first asserted the same arguments as responding to the rejection of *MacLaren et al*, which have been addressed *supra*, and will not be reiterated. Applicants then argue that there is no motivation to combine the references because neither Sanders et al nor Stromberg et al teach a placenta comprising another cell. In response, the rejected claims do not require the presence of another cell, as long as the presence of a mammalian cell which is neither fetal nor maternal in origin. As discussed *supra,* the placenta taught by *MacLaren et al* anticipates or is obvious over the claimed placenta, *Stromberg* and *Sanders* merely provided motivation and means for perfusing such placenta.

Accordingly, the rejection stands.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ram R. Shukla** can be reached on 571-272-0735. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. JANICE LI, M.D.
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QJL
June 15, 2005